

March 1, 2001

Kate-Louise Gottfried, J.D., M.S.P.H.  
Executive Director  
Office for Human Research Protections  
Office of Public Health and Science, OS  
6100 Executive Boulevard, Room 3B01 (MSC 7507)  
Rockville, MD 20892-7507

Dear Ms. Gottfried:

I am writing on behalf of Indiana University, Bloomington in response to the request for comments on OHRP's "draft interim guidance on conflict of interest." We wish to add our support to the comments of the Association of American Universities, the Council on Governmental Relations and the National Association of State Universities and Land-Grant Colleges, in their letter dated March 2, 2001. We share the concerns expressed in that letter that the "guidance" is, at this time, premature. More discussions and information as to the issues under consideration, both substantive and procedural, are needed.

We, at Indiana University, are in the process of strengthening and coordinating our oversight bodies relating to conflict of interests, as well as the other areas of research compliance. But time is needed to both absorb and respond responsibly to the new regulations already issued and pending in the area of ethical conduct of research, especially in the area of human subjects research.

Finally, I want to emphasize the point made in the AAU letter that shifting the primary responsibility for conflict management resolution to the IRBs is a significant burden for IRBs already over-taxed. This proposed shift needs to be analyzed far more carefully in terms of its potential negative effects.

Very truly yours,

Ann J. Gellis  
Associate Dean for Research Compliance  
Office of Research and  
University Graduate School  
Indiana University, Bloomington